ISO 9001:2015 – Preparing For A Successful Transition

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Please note:

- All participants have been muted.
- Please type your questions in the “Question” section of the dashboard – we will make time for as many questions as possible at the conclusion of this presentation.

Overview of topics

- Where do these standards come from?
- Why are things changing (again!)
- What is the timeline for transition?
- What are the key changes?
- Do we have to overhaul our current system?
- FAQs from past presentations
- Final points
- Questions

Where do these standards come from?

- The International Organization for Standardization (ISO) is a collective made up of numerous international members;
- Each standard is assigned a Technical Committee (TC) for authorship;
- TC 176 is the Technical Committee assigned to ISO 9001;
- TC 176 includes members from each of the major industrialized nations;
- American National Standards Institute (ANSI)

Why are things changing (again!)

- The ISO recognizes that the needs of the industries that utilize ISO 9001have evolved (and will continue to evolve) based on changing needs from those industries.
- There is a desire to promote continued adoption of the ISO 9001 standard into more and more sectors and industries.
- There has been a targeted effort to simplify language used to aid in understanding and promote consistency.
- It was recognized that there was a desire to improve the cross-compatibility between standards for companies that wished to achieve more than one certification (ISO 9001, ISO 14001, etc.)

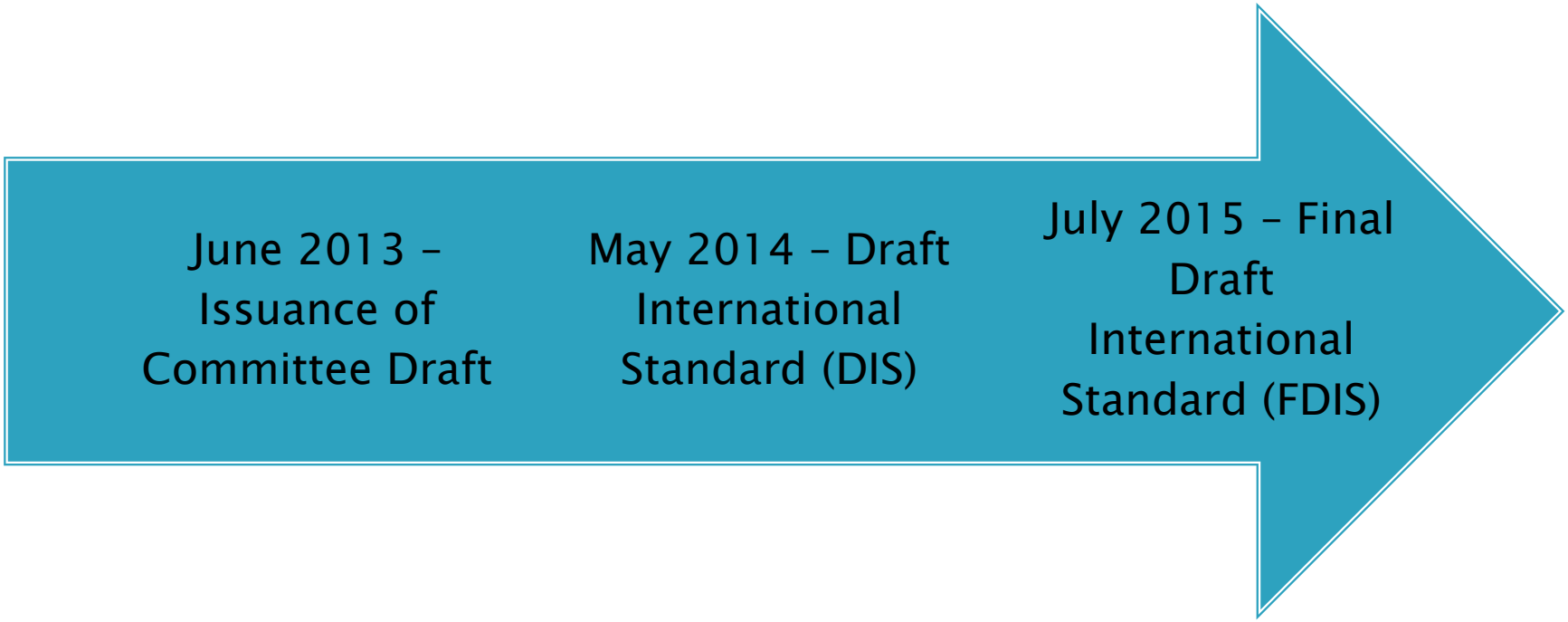
The three goals most important to TC 176 and the ISO at large

- Nigel Croft (the TC 176 chairperson) recently expressed the following as the three key features that TC 176 wants the ISO 9001 standard to have:
  - Foster a Process Approach (systematic, management, results based, consistency)
  - Foster a cycle of Plan-Do-Check-Act (both at the process and system level)
  - Foster Risk Based Thinking (preventing undesirable outcomes)
- Of these, the first two are familiar from ISO 9001:2000 and ISO 9001:2008. The third is new.

What is the timeline for transition?

- The development of the ISO 9001 standard is nearing the end of a long term process with several key dates as shown on the next two slides.

Transition timeline (past dates)



Transition timeline (planned dates)

Current stage – FDIS

- The FDIS was published on schedule in early July 2015. It is available for purchase directly from the ISO (purchase not recommended.)
- Current work includes incorporation of all comments (from all voting members including those that approved and rejected the FDIS.)
- The final push is now being made to incorporate the last of the comments into the final published ISO 9001:2015 standard.
- Our analysis has concluded that FDIS 9001 does not represent a dramatic shift or change from the content that was present in the DIS 9001 document.

Key things to keep in mind

- The transition timeline does not take hold until the final standard is published.
- The September 2018 cut-off likely means that registrars like PJR will have to establish a cutoff date for clients to perform a transition audit. Such provisions will vary from case to case.

Transition Audit Requirements

- In May 2015, PJR's management team met to discuss the needed additional audit time to properly assess a quality management system that has transitioned from ISO 9001:2008 to ISO 9001:2015.
- Our analysis has concluded that for most companies a small amount of additional audit time will be sufficient.
- Each of our clients will be advised on an individual basis what additional time will be required.

What are the key changes?

- ISO 9001:2015 will be among the first ISO standards to make use of the standardized structure represented by “Annex SL.”
- Annex SL has also been referred to as the “High Level Outline” or “Annex XL.”
- Annex SL is part of a larger ISO publication called “ISO/IEC Directives Part 1 – Consolidated ISO Supplement – Procedures Specific to ISO.”
- ISO/IEC Directives Part 1 (and Annex SL therein) can be found here:
- http://www.iso.org/sites/directives/directives.html#toc_marker-76

More details about Annex SL

- Annex SL was first published in 2012 and represented the output of a special committee of the ISO called the Joint Technical Coordination Group (JTCG.)
- A 10 section “blueprint” for authoring all of the ISO family of standards.
- Annex SL promotes (among other things) utilization of common terms and core definitions.
- Eventual plan calls for full transition of all ISO standards to Annex SL structure by 2016 or 2017.

Annex SL's 10 section structure (1-4)

- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Context of the organization
  - understanding the organization and its context
  - understanding the needs and expectations of interested parties
  - determining the scope of the quality management system
  - quality management system and its processes

Annex SL's 10 section structure (5-6)

- 5 Leadership and Commitment
  - general
  - customer focus
  - policy
  - organizational roles, responsibility and authority
- 6 Planning
  - actions to address risks and opportunities
  - quality objectives and planning to achieve them
  - planning of changes

Annex SL's 10 section structure (7–8)

- 7 Support
  - resources
  - competence
  - awareness
  - communication
  - documented information
- 8 Operation
  - operational planning and control
  - requirements for products and services
  - design and development of products and services
  - control of externally provided processes, products, and services
  - production and service provision
  - release of products and services
  - control of nonconforming outputs

Annex SL's 10 section structure (9–10)

- 9 Performance evaluation
  - monitoring, measurement, analysis and evaluation
  - internal audit
  - management review
- 10 Improvement
  - general
  - non-conformity and corrective action
  - continual improvement

What are the key changes?

- The following pages provide insight into the primary “new” content areas represented by ISO 9001:2015.

Risk (the scary new requirement)

- The term “risk” is used 16 times in the auditable portion of the FDIS 9001;
- Identification and management of risk is being viewed as a new system wide strategy in much the same light that Continual Improvement was when ISO 9001:2000 was published.
- A formal/documented Risk Management Process is NOT specifically required.
- Expands the idea of Risk aversion to one that affects all of the various areas of the Quality Management System.

Risk

- Clause 6.1.1 of the FDIS 9001 standard states:
  - *When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:*

    a) give assurance that the quality management system can achieve its intended result(s);

    b) enhance desirable effects;

    c) prevent, or reduce, undesired effects;

    d) achieve improvement.

Risk

- Clause 6.1.2 of the FDIS 9001 standard states:
  - *The organization shall plan:*

    a) actions to address these risks and opportunities;

    b) how to:
    - *1) integrate and implement the actions into its quality management system processes (see 4.4);*
    - *2) evaluate the effectiveness of these actions.*

  - *Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.*

NOTE 1
- *Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.*

NOTE 2
- *Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.*

What ISO 9001:2008 requirements most directly correlate to Risk Management?

- There are a number of activities that are required under ISO 9001:2008 standard that are likely going to help you demonstrate compliance to Risk Management. These include:
  - 5.6 Management Review (an assessment of your overall quality system leading to targeted improvement efforts),
  - 7.2.2 Review of Requirements related to the Product (an assessment of customer expectations against your current capabilities with steps taken to resolve discrepancies),
  - 6.2.2 Training (an assessment of competency needs with steps taken to ensure that personnel are fully qualified and competent.)
  - 8.5.3 Preventive Action (an assessment of potential problems with actions taken to avoid those issues in the first place), and

Key changes in terminology

- “Procedures”, “Records”, and “Documents” have all been eliminated in favor of “Documented Information.”
  - The standard is trying to be more inclusive in accepting alternative approaches to these areas.

- All references to “Product” will now read “Products and Services.”
  - This has long been the case already, as clause 3 of ISO 9001:2008 stated “Wherever the term “Product” appears it can also mean Service.”
  - The standard is further pushing the idea of ISO 9001 as being applicable to multiple types of businesses (those with and those without a tangible product.)

Key changes in terminology

- "Management Responsibility" has become "Leadership
  - Pushes further the concept that Management must lead by example and involvement, rather than simply directing that activities are performed.

- "Continual Improvement" has evolved into a larger section called "Improvement"
  - Promotes the concept that Continual Improvement is not the only aspect of improvement strived for in a quality system (improvement can also be characterized by breakthroughs, reactive changes, and reorganizations.)

Key changes in terminology

- Suppliers are now referred to as “External Providers”
  - This is intended to better accommodate service organizations.
  - The explanation provided in FDIS 9001:Annex A, clause A.8 indicates that “External Providers” includes the following:
    - Outside suppliers;
    - Associate companies; and
    - Outsourcing.

Elimination of required content

- ISO 9001:2015 will not specifically require any of the following:
  - Quality Manual
  - Procedures Manual
  - Work Instructions

- Organizations could theoretically achieve certification without any of these documents, however auditors will still be required to verify consistency with the applicable requirement, consequently the organization will need to be prepared to show a **consistent, effective process** for whatever activity is being reviewed.

- If this can be accomplished without a procedure/quality manual, it will be accepted.

Elimination of the Management Representative

- The title of “Management Representative” does not appear within the ISO 9001:2015 standard.
- The implication is not that this responsibility has been eliminated, but rather that many of this party’s key functions should now fall to top management itself.
- An organization can certainly appoint a “key” person (arrangements for audits, key contact for corrective actions, etc.,) but the management of the quality management system should NOT be solely that person’s responsibility.
- This reflects the current “in practice” arrangement for many of the companies already certified.

Elimination of Permissible Exclusions

- ISO 9001:2015 has removed all verbiage related to “Permissible Exclusions.”
- Organizations can now claim any item from ISO 9001:2015 under a “Non-Applicable” designation.
- This means that the validity of such designations will be verified at each audit.
- In practice – not terribly different from current approach, except that the scope of what can be claimed for exemption now encompasses the entire standard. Your current method for documenting these very likely will not change.

The introduction of "Interested Parties"

- ISO 9001:2015 will include a new term that is intended to be applied to all Annex SL based standard – "Interested Parties."
- The preliminary definition of this term is as follows:
  - *"Person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity."* Examples given include customers, owners, people within the organization, suppliers, bankers, unions, partners, and even competitors.
- Clause 4.2 requires that organization determine who their interested parties are, but emphasizes "relevant to the quality management system."
- The intention is that as an organization, you will ensure that your quality management system considers all relevant input requirements. The term "Interested Party" is intended to broaden the scope of who such requirements might come from.
- In practice, this will not require a great deal of additional implementation activity on the part of the organization. Ensuring that you are cognizant of all applicable requirements is simply good business.

Let's look at some key new questions posed by the ISO 9001:2015 standard:

Most key changes are found in Sections 4, 5, and 6

Section by Section

- Sections 1-3 – Not specifically auditable (as before)
- Section 4 – Context of the Organization
  - Similar to ISO 9001:2008 4.0 – Quality Management System
- Key new questions:
  - *What purpose does the organization serve?*
  - *Who does it exist for?*
  - *Who are the interested parties?*
  - *Does any part of the ISO 9001:2015 standard qualify for a "non-applicable" designation?*

Section by Section (cont.)

- Section 5 – Leadership
  - Uses strong language related to top management's involvement in the quality management system.

- Key new questions:
  - *Is a Leadership structure evident?*
  - *Has Leadership made itself accountable for the effectiveness (or lack thereof) of the QMS?*
  - *Has Leadership ensured that the Quality Policy/Objectives are consistent with the strategic direction of the company?*
  - *Has the QMS been integrated into the business processes?*

- Please note that this does NOT mean that your financial records will be subject to audit.

Section by Section (cont.)

- Section 6 – Planning for the quality management system
  - Planning is viewed in a whole new light – taking into account the new concept of risk.

- Key new questions:
  - *Have all risks (and opportunities) been considered?*
  - *Have actions been taken or planned for said risks?*
  - *With regards to Quality Objectives –*
    - *Who will be responsible?*
    - *What is the target date?*
    - *What is to be accomplished?*

Section by Section (cont.)

- Section 7 – Support
  - Borrows heavily from ISO 9001:2008 Section 6.0 – Resource Management, as well as bits and pieces from Section 4 and 5.

- One very slightly new area of content is provided in clause 7.1.6 that asks the following key question:

  - *"Has the organization considered changing needs and trends against its current competency base and determined what is needed for the future?"*

  - No other significant new content that hasn't been present in some form already in ISO 9001:2008.

Section by Section (cont.)

- Section 8 – Operation
  - Very similar to ISO 9001:2008 Section 7.0 – Product Realization, as well as bits and pieces of Section 8.0
  - No significant new content that hasn't been present in some form already in ISO 9001:2008.

Section by Section (cont.)

- Section 9 – Monitoring, Measurement, Analysis, and Evaluation
  - Very similar to ISO 9001:2008 Section 8.0 – Measurement, Analysis, and Improvement, while also using content from Section 5.0 – this is now where Management Review (5.6) is found.
  - No significant new content that hasn't been present in some form already in ISO 9001:2008.

Section by Section (cont.)

- Section 10 – Improvement
  - Very similar to ISO 9001:2008 Sections 8.5.1-8.5.2- Continual Improvement and Corrective Action.
  - No significant new content that hasn't been present in some form already in ISO 9001:2008.

As you can hopefully see!

- The changes to the ISO 9001 standard are actually minimal and quite manageable.
- Even the “new” idea of risk is not so new if one considers the fact that Preventive Action has been a part of the ISO 9001 standard since it was first published.

FDIS 9001 enables us a first look at the finalized structure of ISO 9001:2015

- The final ISO 9001:2015 will very likely bear almost no distinguishable difference to the current FDIS 9001. This gives us assurance that the following structure is reliable and can be discussed in session as pending and binding.

- The next several slides represent a “cover to cover” analysis of the content of FDIS.

FDIS 9001 – Cover to Cover

- Introduction Section
  - 0.1 – General: Provides an overview statement, intentions on whom the standard benefits, introduces the ideas of Risk Based Thinking, PDCA, and explains four key terms (three of these are getting official definitions for the first time):
    - Shall – mandatory requirement (numerous instances);
    - Should – recommendation (no uses within the auditable content);
    - May – permission (this term appears once in the auditable content); and
    - Can – possibility or capability – numerous instances.

FDIS 9001 – Cover to Cover

- Introduction Section
  - 0.2 – Seven Quality Management Principles – reference to the ISO 9000 standard is given:
    - Customer Focus;
    - Leadership;
    - Engagement of People;
    - Process Approach;
    - Improvement;
    - Evidence-Based Decision Making; and
    - Relationship Management.
  - 0.3 – Process Approach – reinforcement of the process approach an improved graphic therein. Reinforcement of Plan-Do-Check-Act (PDCA) and an improved graphic therein.

FDIS 9001 – Cover to Cover

- Introduction Section
  - 0.3.3 – Risk Based Thinking – definition and explanation of importance
  - 0.4 – Relationship with other management system standards (ISO 9000 and ISO 9004)

FDIS 9001 – Cover to Cover

- Section 1 – Scope – General verbiage related to the applicability of ISO 9001;
- Section 2 – Normative Reference – Linkage to ISO 9000:2015 for all official terms and definitions;
- Section 3 – Terms and Definitions – currently without content, but could be used as a future placeholder for ISO 9001 specific definitions.

FDIS 9001 – Cover to Cover

- Sections 4-10 – As previously reviewed;
- Annex A – Informative – Several key points of information and counsel to be found here, including:
  - A.1 – Structure and terminology – reinforces the doctrine that an organization does not have to align their documentation to match ISO 9001:2015, nor does it have to use the specific terms found in the standard;
  - A.2 – Products and services – a fuller explanation of intent in changing all references of "product" to read "products and services";
  - A.3 – Understanding the needs and expectations of interested parties – a more full explanation of intent in the identification of interested parties;
  - A.4 – Risk based thinking– an extensive section intended to assist in the more full understanding of this concept, emphasizing that a formal structure/process for Risk Management is not required;

FDIS 9001 – Cover to Cover

- Annex A continued
  - A.5 – Applicability – Further discussion on the logic for removing "exclusions" from the ISO 9001 standard and the new concept of "non-applicables"
  - A.6 – Documented Information – Further discussion on the new term that has replaced "Procedure", "Record", and "Document";
  - A.7 – Organizational Knowledge – An explanation of requirements pertaining to competency and ongoing competency through various challenges an organization might face;
  - A.8 – Control of externally provided products and services – Provides an expansive explanation of this phrase and who it applies to.

FDIS 9001 – Cover to Cover

- Annex B – Further, extensive discussion on the relationship between ISO 9001 and other publications (ISO 9004, ISO 10001, etc.)

- Bibliography

Do we have to overhaul our current system?

- Certainly not!
- As previously mentioned, one of the goals of the TC176 committee in writing the new standard was to improve its inclusiveness.
- Telling over 1,000,000 world-wide registered firms that they have to overhaul their system doesn't seem terribly inclusive, does it?

If it works, keep it!

- Your quality manual fits your business?
  - Keep it!
- Your procedures are effective at defining your key processes and how they operate?
  - Keep them!
- Quality Policy, Quality Objectives, etc. are all well known and adding value?
  - Keep those too!

FAQs from past presentations

- The next several slides include key FAQs that have come up in past offerings of this training and the answers to those questions.

Will our staff have to complete transition training?

- It will depend on the extent of revisions that you make to your quality management system, but generally – yes you will be expected to provide some form of transition training to your staff.
- At a minimum, PJR would expect that awareness training of the new standard would be provided, as well as an assessment of the new standard's impact on the various processes and personnel.
- It is entirely conceivable that the majority of your staff will feel no effect from your company's transition to ISO 9001:2015.

What about our internal auditors, will they have to complete transitional training?

- Internal auditing is viewed in the same light as any other required competency within a quality management system. Namely, the organization is responsible for determining what competencies are required for its internal auditors, as well as the methods to be used to achieve those competencies.
- To put it more plainly, each organization will have to decide on its own the extent to which transition training will be needed.
- It is conceivable that a seasoned team of internal auditors could complete a period of self-study and successfully transition to auditing ISO 9001:2015.
- As has always been the case, the competency of your internal auditors will be judged by the overall effectiveness of your internal audit process.

Will the other standards (AS9100, TS16949, etc.) be updated also?

- All of the major sector specific standards, including TS 16949 (automotive), AS9100 (aerospace), and TL9000 (telecommunications) have indicated their intentions to transition and continue their alignment with ISO 9001.

- The timelines for these other standard updates are not fully known at this time, but a 2016 publication date seems likely for all three.

- At present the only major standard that is not planning to continue its alignment to ISO 9001 is ISO 13485 (medical devices,) which is in the midst of its own update with a targeted publication of early 2016.

Should we get certified now or wait?

- There are many companies at various stages of implementing a new quality management system in accordance with ISO 9001:2008 that may be wondering if there is still value in registering to ISO 9001:2008.
- While PJR cannot make the final decision for you, it is important to bear in mind that ISO 9001:2008 still has at least 3 years of usability left in it.
- It is also important to bear in mind that the very first audits later this year to ISO 9001:2015 will be a bit more difficult for both auditee and auditor.
- With the passage of time, auditors will be more comfortable auditing ISO 9001:2015, ensuring an even smoother transition.

What steps can we take right now?

- The International Accreditation Forum (IAF) has published an Informative Document (ID 9) which recommends the following steps be taken in a transition to ISO 9001:2015.
  - 1) A full review of the ISO 9001:2015 standard should be performed by Top Management to identify the gaps that need to be addressed.
  - 2) A plan of implementation should be developed with assigned responsibilities.
  - 3) All quality management system documents (including the quality and procedures manual (if applicable)) should be updated to reflect any new or revised processes.
  - 4) All necessary awareness and transition training should be completed.
  - 5) A full system internal audit followed by a Management Review should be complete.
  - 6) Corrective Actions for all internal audit findings should be in process or complete.
  - 7) Coordination with PJR for planning of transition arrangements.

Final point on document transition

- Make sure that your existing documentation (Quality Manual, Procedures, etc.) works for you first and foremost.

- If a re-numbering enables the documentation to work better for you, than do so, but it will not be required.

Work with your auditor

- Particularly in times of transition, auditors provide expert analyses of a quality management system against audit criteria.

- Your auditor will be a valuable resource in your transition process.

Looking ahead

- This is an exciting time for quality system certification. ISO 9001:2015 promises to be a beneficial update to a standard with a long track record of contribution to the world.

- PJR will continue to provide timely updates on the transition process and will endeavor to enable our clients as smooth a transition as possible.

Further information:

PJR has prepared two reports that we feel will be very beneficial to our clients, these are:

- An side by side comparison between ISO 9001:2008 and FDIS 9001:2015; and
- An FAQ report highlighting key questions and answers,

Both of these items can be found on our website – www.pjr.com

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